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DIAGNOSTIC INFORMATION: AN UNPOLISHED JEWEL

23-25 JAN.
2018
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The EGG
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A MedTech Europe event

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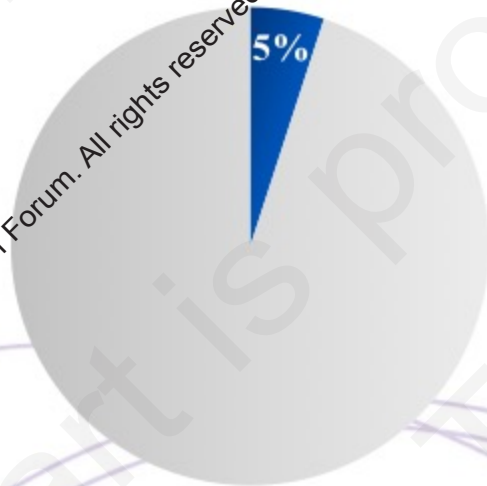
bringing HealthTech stakeholders together

**DIAGNOSTIC INFORMATION:
AN UNPOLISHED JEWEL**
**In Vitro Diagnostics have a
story to tell,
the patient & clinician viewpoint.**

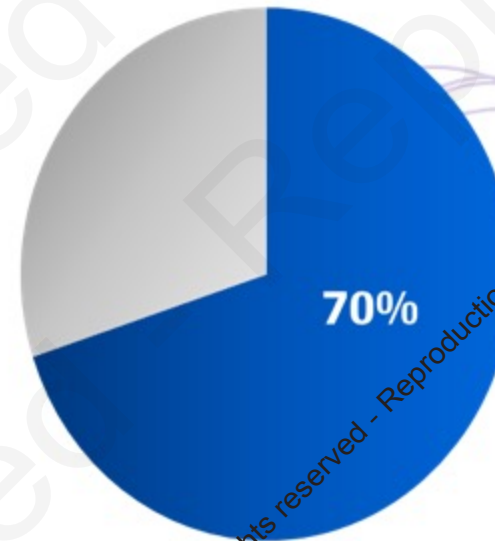
The Value of Diagnostics

IVD's underestimated*

Hospital costs



Healthcare decision-making



In on average 75% of patients, IVDs are used**

* Wolcott, J. & Goodman, C. (2009). The Value of Laboratory Screening and Diagnostic Tests for Prevention and Healthcare Improvement. Health Technology Report. The Lewin Group.

** DOI: 10.1371/journal.pone.0149856

Uses of diagnostic tests in the patient pathway.

The economic, medical and societal benefits of IVD tests are often overlooked



IVDs improve patient care, contribute to protecting consumer health, help to limit healthcare spending.

* Between brackets (Proportion of IVD use)

Screening: Hepatitis C in Europe

50% of HCV infections remain undiagnosed



50% DIAGNOSED

CAN NOW BE CURED



50% UNDIAGNOSED

TRANSMISSION

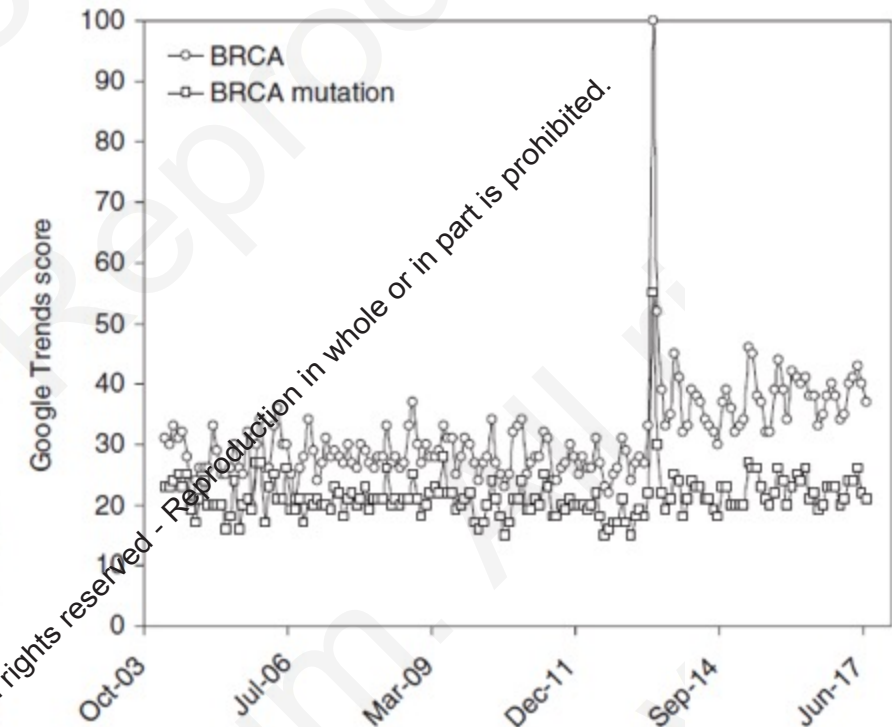
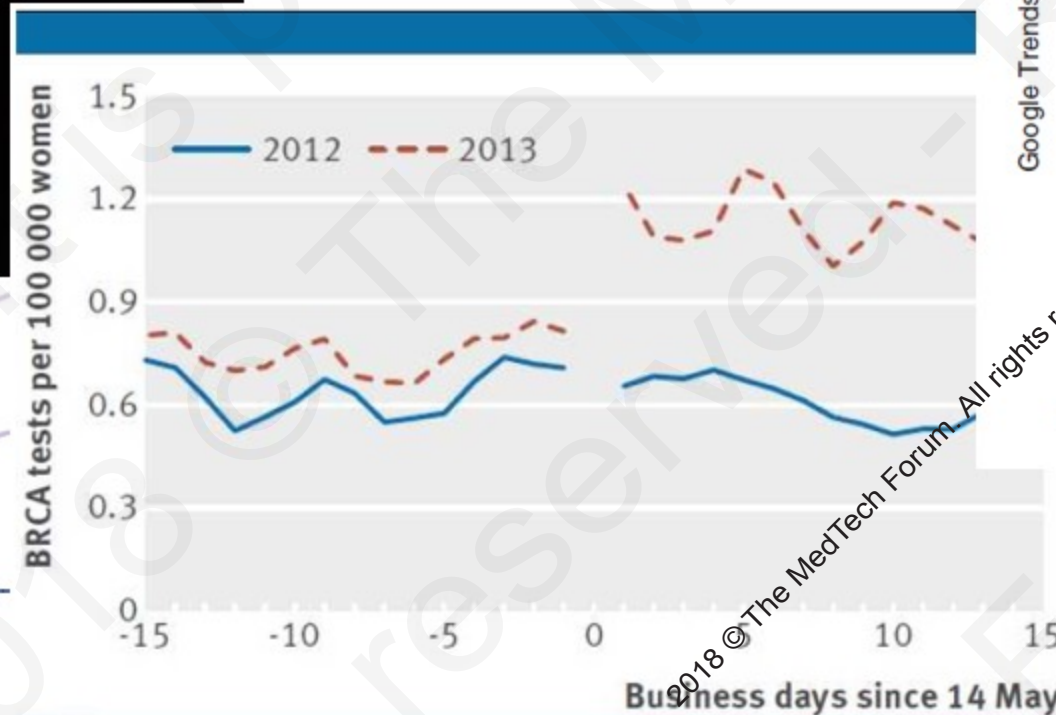
DISEASE PROGRESSION

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Risk stratification: “Angelina Jolie effect”

Oncogenic mutations in the BReast CAncer genes are associated with a high risk of developing breast and ovarian cancers



The role of guidelines in diagnostic approaches

Diagnostic uncertainty is common in heart failure patients with dyspnea¹

Heart Failure (HF) symptoms are often non-specific.

This makes it hard to discriminate between HF and other conditions.

Symptoms are difficult to interpret in the obese, elderly and patients with chronic lung disease.

Major heart failure guidelines recommend Natriuretic Peptide (NP) testing (**CLASS I, LOE A**), BUT

ESC, European Society of Cardiology; HF, heart failure; NP, natriuretic peptide

1. McMurray, J.J. et al. (2012). *Eur Heart J*, 33, 1787-1847.
2. Thygesen, K. et al. (2012). *Eur Heart J*, 33, 2001-2006.

*Every person is unique.
So is every cancer.*

Stock photo. Posed by model.

250

types of cancer ¹

350

genes that contribute to
cancer development ²

100,000

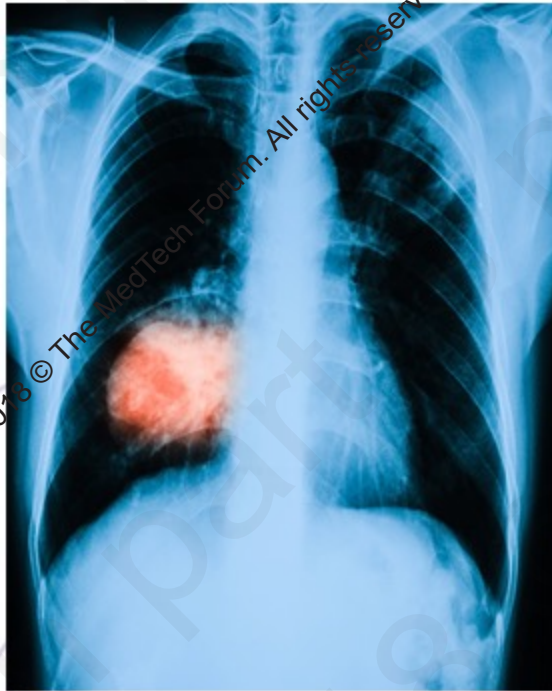
mutations (approx.) found in
some types of lung cancers³

1

unique cancer profile

The value of understanding disease mechanisms

Diagnose of LUNG CANCER



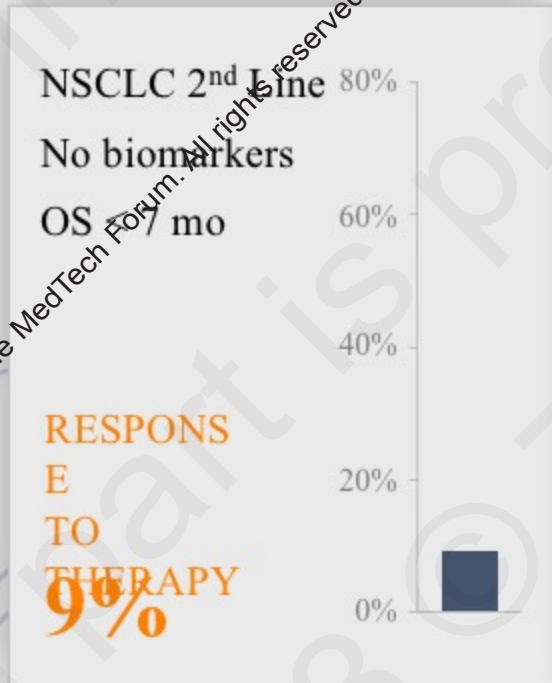
In 2014, the expected number of tests for cancer in the UK population was 59,294, but the provision of testing was only 34,675, i.e. a difference of around 24,000 tests.

This included 16,000 patients with NSCLC who would have been eligible for testing.

Of these patients, 3,500 would have been eligible for targeted medicines that could have prolonged their progression-free survival, but missed out.

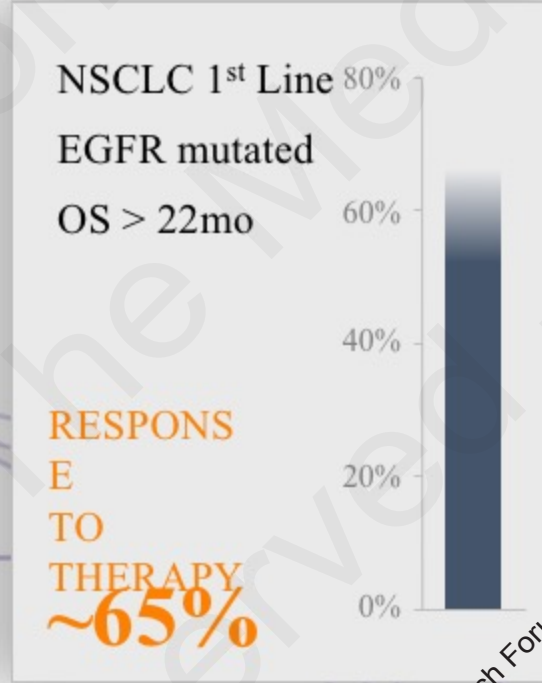
The value of understanding disease mechanisms

2005¹



OS: Overall Survival

2012²



OS: Overall Survival

2017³



PFS: Progressive Free Survival

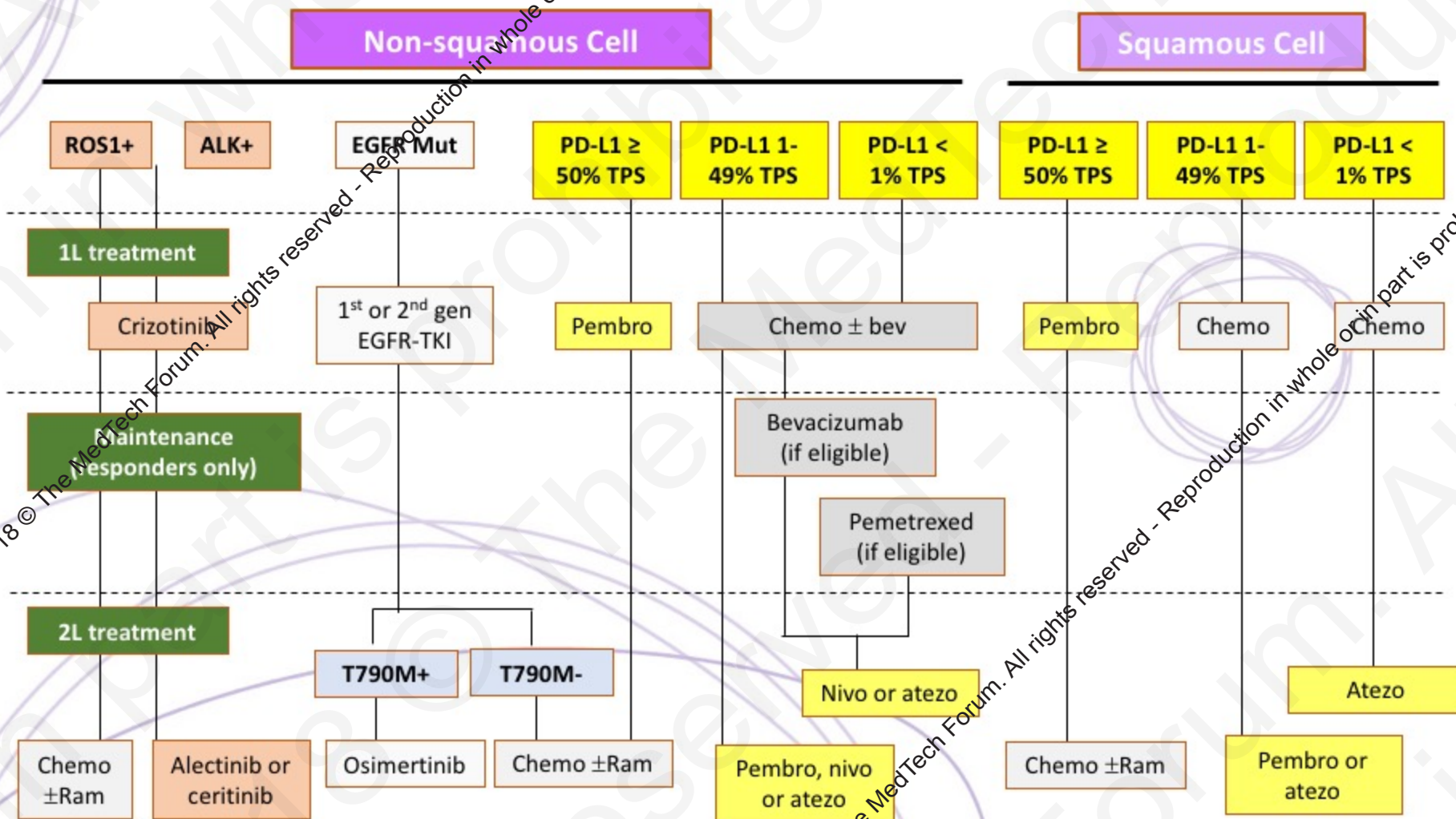
1. Shepherd FA, et al. NEJM 2005; 353 (2): 123-32 (Tarceva)

2. Rosell R, et al. Lancet Oncol 2012; 13: 239-46 (Tarceva)

3. Ramalingam S, et al. Presidential Symposium I of the ESMO 2017 Congress; September 8 -12; Madrid (3rd Generation)

BUT ... clinicians would be lost w/o diagnostic testing

Non Small Cell Lung Cancer treatment becomes complex



Adapted from presentation by Sylvie Lantejoul at ELCC 2017

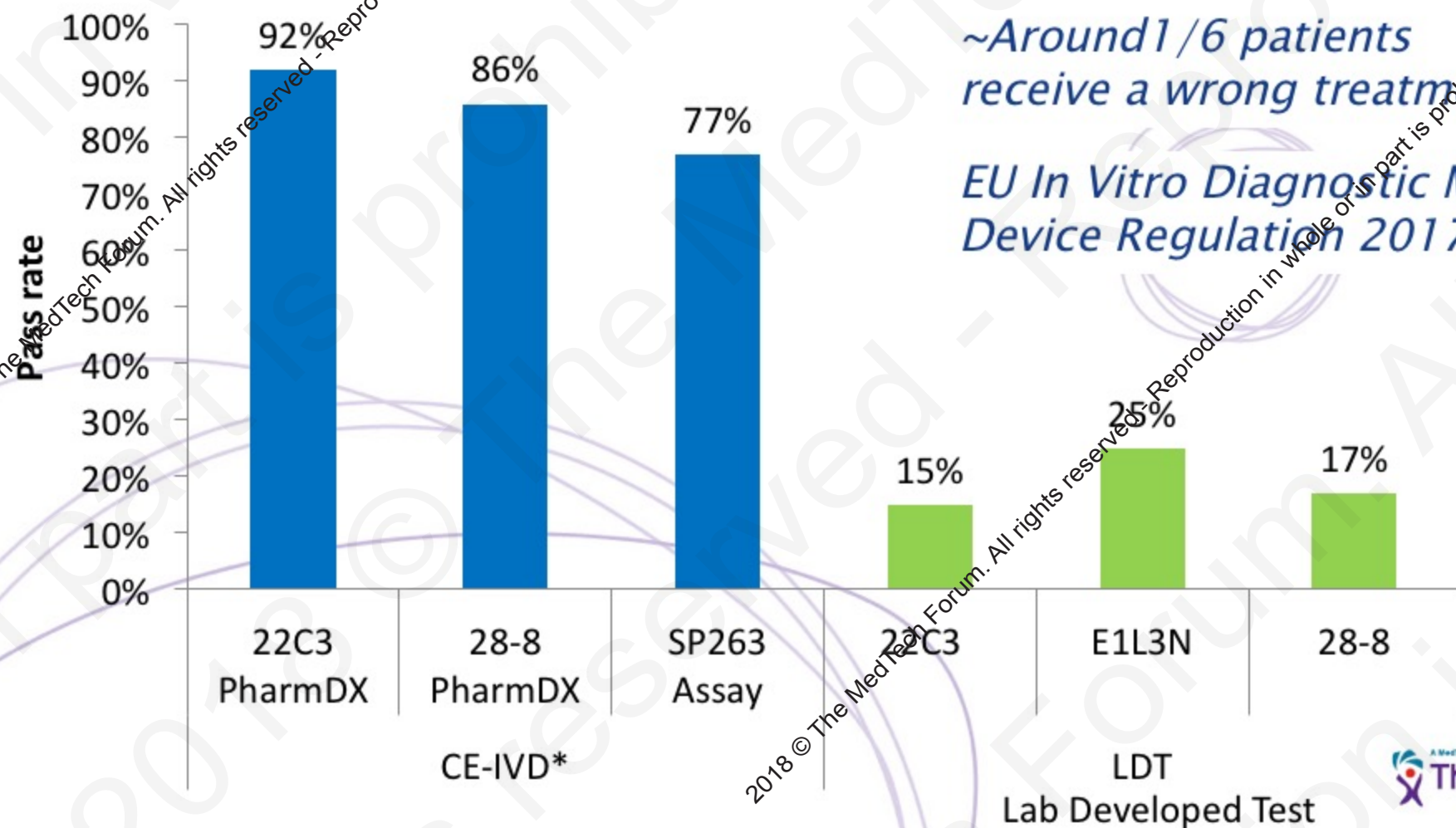
Increased collaboration between Pharma & Diagnostics companies in Immunotherapy

PD-L1 Assays: A complex & dynamic landscape

	Ventana (SP263)	Ventana (SP142)	Dako (28-8)	Dako (22C3)
Product Name	VENTANA PD-L1 (SP263) Assay	VENTANA PD-L1 (SP142) Assay	PD-L1 IHC 28-8 PharmDx	PD-L1 IHC 22C3 PharmDx
Pharma Partner & Associated Drug	 Durvalumab   Nivolumab	  Atezolizumab	  Nivolumab	  Pembrolizumab

BUT what if no CE IVD tests are used?

False positive or false negative test results will generate more anxiety, distress, sometimes unneeded surgery or unnecessary treatments



~Around 1/6 patients receive a wrong treatment

EU In Vitro Diagnostic Medical Device Regulation 2017/746.

New technologies like Next Generation Sequencing will make it more complex but will also bring more medical information to the patient and clinician.



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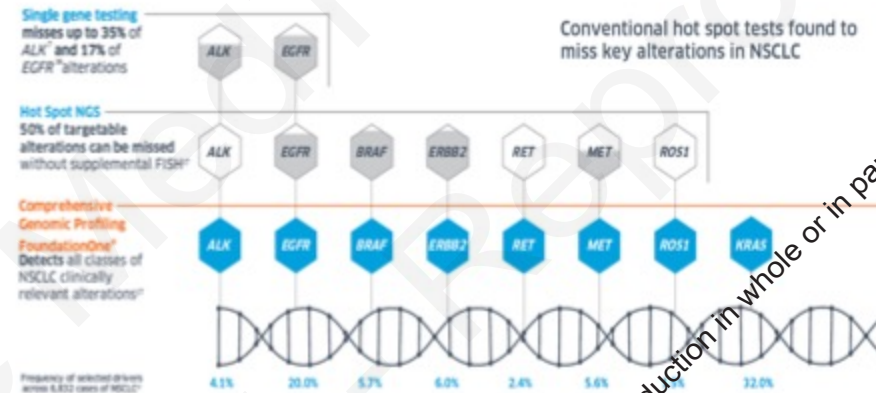
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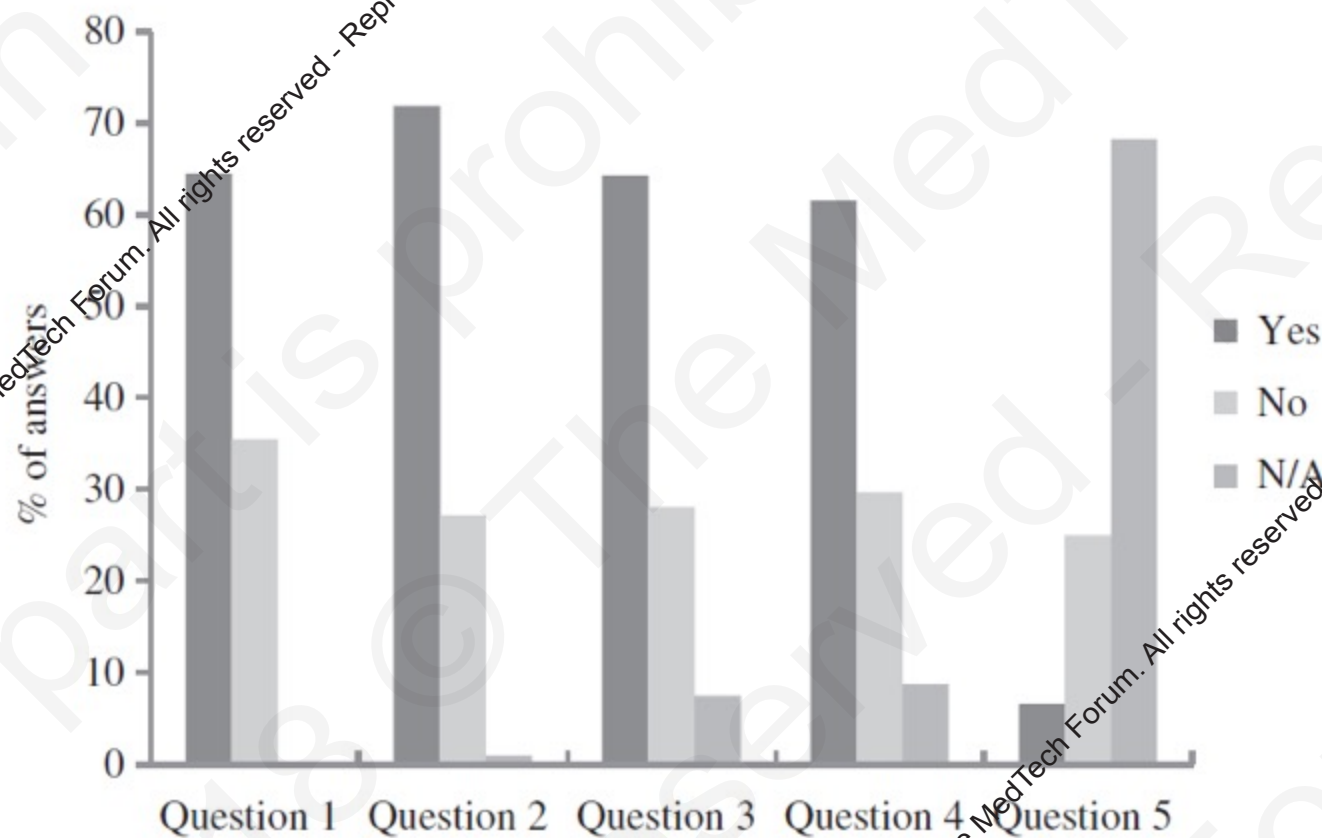
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[See stories that inspire us.](#)



Patients and the complexity of laboratory testing

Patients are interested in receiving their laboratory medicine results, the majority with explanatory notes.



1. Ian D. Watson, et al. Clin Chem Lab Med 2017; 55(10): 1496–1500



Summary

IVDs are an essential part of healthcare decision-making.

Laboratory testing plays an important role from screening to diagnosis to treatment, contributing to the available medical information regarding a patient.

IVDs can limit healthcare spending, which is a major economic issue in every country throughout the world.

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